UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,831	01/25/2006	Junya Toguchida	Q92863	6132

65565 7590 07/09/2008

SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
KUDLA, JOSEPH S	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,831	TOGUCHIDA, JUNYA	
	Examiner	Art Unit	
	JOSEPH S. KUDLA	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *29-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/28/06 and 1/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election without traverse of Group I, encompassing claims 11 and 20-31 and the species (5Z, 9β, 11α, 13E)-17,17-propano-11,16-dihydroxy-9-chloroprosta-5,13,19-trienoic acid, in the reply filed on 3/27/08 is acknowledged.

However, within the reply, Applicant submitted that the basis of the intervening reference for breaking the Lack of Unity was overcome by submittal of a sworn English translation of JP-2003-280191, thus perfecting the priority date to 7/25/2003. Therefore, the Examiner submits Paralkar (European Patent Application EP 1 205 189 and cited by Applicant). Paralkar teaches a method of promoting bone growth comprising a prostaglandin agonist which is an EP2 selective agonist (reference claims 9 and 10). Paralkar also teaches that a representative use of the therapy comprising an EP2 selective agonist is to limit or treat cartilage defects or disorders (page 4, paragraph 38). Because an EP2 selective agonist is shown to treat cartilage defects or disorders, Paralkar teaches a method of treating a cartilage-related disease as in instant claim 11. Therefore, the instant claims do not have a special technical feature and thus the claims lack unity.

The requirement is still deemed proper but is Non-Final.

2. Applicant's election of Group I, encompassing claims 11 and 20-31 and the species (5Z, 9β, 11α, 13E)-17, 17-propano-11, 16-dihydroxy-9-chloroprosta-5, 13, 19-trienoic acid, in the reply filed on 3/27/08 is acknowledged. The inventions contained in Groups II-IV, encompassing instant claims 32-34 and the non-elected subject matter

contained in claims 29-31, are withdrawn from consideration as being drawn to non-elected subject matter. See 37 CFR 1.142(b).

Accordingly, the subject matter now under consideration is drawn to claims 11 and 20-28.

Priority

This application is a national stage entry of PCT/JP04/010890, filed on July 23, 2004, which claims benefit of Japanese Patent Application 2003-280191, filed on July 25, 2003. Priority is acknowledged.

Information Disclosure Statement

3. The Information Disclosure Statement (IDS) correspondences submitted by Applicant on April 28, 2006 and January 25, 2006 are acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent.

4. The information disclosure statement filed January 25, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, the references for the foreign cited documents JP 2001-220357, JP 2000-507961, JP 11-193268, JP 2001-527063, JP 2000-95755, JP 2000-128858, WO

98/34916, JP 2002-179595, JP 6-227985, WO 02/16311, WO 02/20462 and WO 03/16254 are not provided.

5. The listing of references in the Search Report is not considered to be a proper citation complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Specifically, Applicants' submission of the search report in the IDS filed April 28, 2006 is incorrect.

6. Applicant should be aware that the examiner has limited time to spend per case and the references provided in the IDS were afforded all of the consideration such time constraints allow. In the interest of reducing the examination burden on the Office, applicant should consider providing page and paragraph notations as to where pertinent information may be found in the references listed on the IDS forms.

7. The listing of references in the January 25, 2006 IDS appear to be a significant duplication of those cited and received in the April 28, 2006 IDS submittal.

Specification

8. The attempt to incorporate subject matter into this application by reference to WO 98/34916, JP-A-61-249951, JP-A-8-239356, US 4,692,464 and US 4,863,961 is ineffective because the root words "incorporate" and/or "reference" have been omitted.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. See 37 CFR 1.57(f).

Drawings

9. The replacement drawings were received on 4/28/2006. These drawings are acknowledged.

Claim Rejections - 35 USC § 112

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The following is a quotation of the second paragraph of 35 U.S.C. 112:
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. The recitation "and/or" in claims 11, 21, 22 and 26 is confusing as to what method is being claimed. *In re Anderegg* 51 USPQ 66.

11. Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. This is a Written Description rejection.

Applicant is attempting to incorporate essential subject matter into the claims by reference to foreign and U.S. patents and publications. Specifically, instant claim 27 discloses "substances having EP2 agonist activity in one or more of the compounds selected from a compound described in WO 98/34916, JP-A-61-249951, JP-A-8-239356, US 4,692,464 and US 4,863,961." However, Applicant has not satisfied the "incorporation by reference" requirement as disclosed in 37 CFR 1.57(b), (c), or (d), therefore, the claims lack written description.

12. Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Instant claim 27 lacks structural information of the compounds which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant discloses species in instant claim 28 which are limitations of instant claim 27 and considered essential to the invention, however, Applicant provides no structural information in instant claim 27 from which to arrive at the limitations of instant claim 28.

13. Claims 11 and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The indication of the group or subject to be treated and the indication for which treatment is given is critical or essential to the

practice of the invention, but not included in the claim(s) is not enabled by the claim. As an example, Claim 11 could be remedied by the addition of a subject or group to which the invention could be administered along with a statement that the therapy is given to stimulate chondrocyte growth. Currently, instant claim 11 reads on anyone, without regard to whether the subject has a cartilage-related disease.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 11 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paralkar (European Patent Application EP 1 205 189 and cited by Applicant), in view of all Tani et al. (“Development of a Highly Selective EP2-receptor Agonist. Part 2:

Identification of 16-Hydroxy-17, 17-trimethylene 9beta-chloro PGF Derivatives," 2002, Bioorganic and Medicinal Chemistry, Volume 10, Pages 1107-1114) and Fortier et al, (Insulin-like growth factor-I enhances cell-based repair of articular cartilage," 2002, J Bone Joint Surg, Volume 84-B, Pages 276-288).

Paralkar teaches a method of promoting bone growth comprising a prostaglandin agonist which is an EP2 selective agonist (reference claims 9 and 10). Paralkar also teaches that representative uses of the therapy comprising an EP2 selective agonist is to limit or treat cartilage defects or disorders (page 4, paragraph 38).

Paralkar does not teach the method utilizing the EP2 agonist species (5Z, 9β, 11α, 13E)-17, 17-propano-11, 16-dihydroxy-9-chloroprosta-5, 13, 19-trienoic acid.

Tani et al. teach (5Z, 9β, 11α, 13E)-17, 17-propano-11, 16-dihydroxy-9-chloroprosta-5, 13, 19-trienoic acid (compound 4c on page 1110, table 2) is a potent and selective EP2-receptor agonist.

Fortier et al. teach insulin-growth factor-I enhances cell-based repair of articular damage (title).

It would have been obvious to one of ordinary skill in the art at the time of the invention that since Paralkar teaches a method of treating cartilage defects or disorders comprising a prostaglandin agonist which is an EP2 selective agonist and Tani et al. teach (5Z, 9β, 11α, 13E)-17,17-propano-11,16-dihydroxy-9-chloroprosta-5,13,19-trienoic acid is a potent and selective EP2-receptor agonist, that administration of (5Z, 9β, 11α, 13E)-17,17-propano-11,16-dihydroxy-9-chloroprosta-5,13,19-trienoic acid would be effective at treating cartilage defects or disorders, thus rendering instant

claims 11, 27 and 28 obvious.

It would have been obvious to one of ordinary skill in the art at the time of the invention that treating cartilage defects or disorders as taught in Paralkar would include inhibiting cartilage calcification, inhibiting cartilage degradation or to stimulate new cartilage, thus rendering instant claim 21 obvious. It would have been obvious to one of ordinary skill in the art at the time of the invention, that if the EP2 selective agonist inhibits cartilage calcification, then the EP2 selective agonist would inhibit osteopontin protein expression, which is responsible for pathological mineralization in articular cartilage, thus rendering instant claims 22, 23 and 25 obvious. It would have been obvious to one of ordinary skill in the art at the time of the invention, that if the EP2 selective agonist promotes cartilage growth, then the EP2 selective agonist would stimulate cyclin D1 protein expression, since cyclin D1 stimulation contributes to increase chondrocyte growth, thus rendering instant claims 22-24.

It would have been obvious to one of ordinary skill in the art at the time of the invention that since Paralkar in view of Tani et al. teach a method of treating cartilage defects or disorders comprising a prostaglandin agonist which is an EP2 selective agonist (see *supra*) and Fortier et al. teach insulin-growth factor-I enhances cell-based repair of articular damage, that a method utilizing a pharmaceutical composition combining the two would similarly be useful in treating cartilage defects or disorders and would render claim 26 obvious. “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of

combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
June 30, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615